Health Information Technology Policy Committee
Final Summary
Of the November 19, 2010, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 18th meeting of the Health Information Technology Policy Committee (HITPC). She reminded the group that this was a Federal Advisory Committee meeting, and was being conducted with the opportunity for public comment. She conducted roll call and turned the meeting over to HITPC Vice Chair Paul Tang.

2. Opening Remarks

Paul Tang welcomed Dr. Barbara Agerwald, a new Committee member from the Department of Veterans Affairs (VA). The Committee approved minutes from its last meeting by consensus. Paul Tang then reviewed the day's agenda.

> **Action Item #1:** Minutes from the October 20, 2010, HITPC meeting were approved by consensus.

3. Quality Measures Workgroup Update

Quality Measures Workgroup Co-Chair David Lansky reported that the Workgroup has convened subject experts on its six tiger teams, covering a wide spectrum of stakeholders. Their overarching goal is to drive toward measurements of patient outcomes and clinical outcomes. The teams developed measure concept areas. One set of criteria focused on HIT-sensitive and HIT-enabled measures: those that would reflect improvements in care that would be assisted by the use of health IT.

David Lansky then presented a series of slides illustrating measure concepts and sub-domains relating to meaningful use in the following areas: (1) patient and family engagement, (2) clinical appropriateness, (3) care coordination, (4) patient safety, (5) population and public health, and (6) other. The Workgroup is reaching out to the measurement community and asking whether it has measurements already in existence that make sense for meaningful use.

The Quality Measures Workgroup will issue a Request for Comment on November 29, 2010, giving the public most of December to respond. Workgroup members will digest that input and then, potentially, ONC will solicit more specific work in this area. This measurement work will be coordinated with efforts of other government agencies to avoid duplicative efforts.

The Workgroup is not intending that Stages 2 or 3 of meaningful use would capture its extensive listing of measurements, and the group hopes that the measurement community will come back with some cross-cutting measures. The Workgroup will present the results of the public comments to this Committee in January or February.

One Committee member asked whether the Workgroup is seeking public comment on the concepts already proposed, or if it hopes that responders will propose specific measures. David Lansky explained that the Workgroup will provide a grid as a response tool and ask responders to provide measures that would be appropriate in specific, relevant areas.

4. Governance Workgroup Recommendations

Governance Workgroup Chair John Lumpkin reminded the Committee that the focus of last month's Governance Workgroup recommendations were the "what" of the governance mechanism. At this HITPC meeting, the Workgroup will discuss the "who" and the "how." He also reminded Committee members that the definition of the Nationwide Health Information Network (NHIN) is a set of policies, standards, and services that enables the Internet to be used to improve health care. The NHIN is an environment of trust and interoperability created by standards, services, and policies. It is the preferred approach for the nation, but participation cannot be mandatory under current law.

John Lumpkin explained that there are two instances when exchange is subject to governance: (1) when it applies to applicable standards, services, and policies; and (2) when those exchanging health information assert that they are doing so under the auspices of the NHIN. Any entity, large or small, engaged in exchanging health information that asserts itself as working under the auspices of the NHIN should be part of the governance process. John Lumpkin noted that groups would want to be a part of this because they would want to feel some comfort and trust in exchanging health information with other groups with which they are not familiar. It will provide a competitive advantage over those who are not exchanging information under this secure framework.

The hope is for some manner of government incentive to encourage the broadest range of entities to participate. In hearings that the Workgroup has held, it is clear that their direction should be towards leveraging across existing federal authorities. Strong federal leadership and engagement is needed, as is a federal role in the coordination of governance policies. This includes the ability to learn and adapt on an ongoing basis. John Lumpkin noted that there will likely be a variety of approaches to validation and enforcement, and that governance should reflect that. There is also the desire to minimize the burden for those who want to participate in exchange, and so coordination among various government authorities will be critical.

He reminded the Committee that it was presented with the set of nine principles for the NHIN at the last HITPC meeting. The objectives of governance are to improve health care while establishing trust, and to ensure interoperability while protecting innovation. The intent is not to identify specific technical specifications, but rather the mechanism for policy governing these. As explained at the last HITPC meeting, the goal is to establish appropriate mechanisms for accountability and enforcement.

Since the last HITPC meeting, the Workgroup has been engaged in addressing the following questions: what existing entities are out there, and where are the gaps? What are the essential functions that the federal government should perform or delegate? If it delegates, then to whom? John Lumpkin acknowledged that in comments the Workgroup has received, it is hearing the need for public education and the use of plain language to explain these concepts. These issues are dense and complex, even for those familiar with HIT issues. Workgroup members also heard that more emphasis is needed on patient safety, and that the greatest concern is privacy and security. Many additional comments encouraged the leveraging of existing mechanisms.

Key findings from public comments also include the need for state and federal partnership as well as the importance of recognizing that some states are already moving forward on the governance front. A public/private collaboration structure, national standards, and a national accreditation program for qualified entities are all needed.

John Lumpkin explained that the ecosystem of NHIN governance functions, noting that the objectives are to engender trust, encourage interoperability, and foster innovation. Its aim is to make the right information available at the right time. The Workgroup identified five domains: (1) policies and eligibility criteria; (2) technical requirements; (3) oversight of governance; (4) assurance of compliance, accountability, enforceability; and (5) provision of support for implementation. He then outlined a series of general recommendations as well as recommendations focused in the following areas: roles and responsibilities, conditions of trust and interoperability, the federal role, the non-governmental role, the validation role, and the relationships among these roles.

In discussion, the following comments were made:

- National Coordinator for Health Information Technology David Blumenthal noted that the validation role is fairly straightforward: if the federal government is going to recognize exchange entities in the nature of consumer protection and public assurance, then it needs to identify or develop the mechanism for doing so, and also for de-validating those who are not measuring up to the standards set forth.

- David Blumenthal asked for clarification on the implementation role, given that there does not appear to be any particular enforcement authority with this group. John Lumpkin explained that the Workgroup initially thought of this as coordination role, noting that there was a fair amount of concern that giving dispute resolution authority to a non-government entity might be inhibitory. However, the group recognized that once the conditions of trust and interoperability exist, exchanging entities will begin to identify technical policies and requirements that work for them, and they may want to use these as part of their process within their sub-community.

- Deven McGraw clarified that these efforts are establishing a more robust advisory process for gathering recommendations and reporting to the ONC, and not vesting a private organization with greater governance authority. She asked who is envisioned as being a validation entity, and who will have oversight of these entities. John Lumpkin explained that

the entity could take a number of forms. It may be the role of the validation process not to redo things already being done by the Privacy and Security Tiger Team—there may be other areas where the technical components of that exchange need to be validated. The first step will be for the ONC to identify the criteria for validation. Then, the non-government body would carry out the validating, with multiple pathways to validation. The hope is to minimize duplication and the burden on those who wish to exchange.

- John Lumpkin explained that the ONC would select a non-governmental body and delegate authority to it to issue validations, based on the policies, procedures, and conditions that are established at the federal level. This non-government body may serve as the overarching entity, delegating other specific entities that can also do the work. It would be an interconnected structure.

- Paul Egerman asked how this process would work for entities that operate outside the scope of the ONC, such as independent labs and retail pharmacies. John Lumpkin commented that this points to the issue that the ONC would set conditions for trust and interoperability, and the criteria for validation would be based on those. Participation in this environment of policies, procedures and standards is strongly encouraged and incentivized by the federal government, but it is not required. A lab may want to participate, at which point there may be an entity that could verify whether that lab is licensed, meeting requirements, etc.

- In response to a question, John Lumpkin said that the Workgroup did not specifically address the interrelation of validation entities with enterprise-level provider directories. Paul Egerman suggested that the directory could serve a registrar function, with validation being used as a tool for inclusion in the directory.

- Charles Kennedy asked how the validation role would interact with the electronic medical record (EMR) certification process, if at all. John Lumpkin suggested considering the leverage the currently exists: if an entity is using a certified electronic health record (EHR) that meets meaningful use, then there would be no need to further validate that component. With regard to governance from end to end, it may be that within a community there is a statewide health information exchange (HIE). The validation process would include the process of confirming the fact that members are exchanging in a way that meets the necessary requirements. The Workgroup is not attempting to shape the governance as the granular level to the point that it addresses how labs or other players participate.

- Charles Kennedy explained that the California State entity is using the provider registry to carry out some of the validation activity. However, he noted that there are many other markets and information exchange layers that do not have this kind of oversight. John Lumpkin commented that if there is validation at the state level, the interplay between federal and state will be complex. The longer it takes for there to be conditions of trust to be established at the federal level, the more likely it is that there will be a state having a significant variance. Most states build off the federal model.

- Christine Bechtel indicated that she was one of the Workgroup members who were not fully comfortable with the notion of the validating body being a non-government entity (NGO) or

a public-private entity. This entity needs to be trusted. She commented that one of the entities widely acknowledged to be a candidate for this role is the National e-Health Collaborative. Some of the Workgroup members have strong leadership ties or types of relationships with this organization. She emphasized that she was not questioning anyone's integrity, but wanted to inform the Committee so that this was a transparent process. She added that if this body is to be successful, this concern must be addressed. John Lumpkin clarified that the Workgroup had no discussions about any particular organization serving in this validating entity role, and disagrees with Christine Bechtel about whether any entity that currently exists could play that role.

- In response to a question, John Lumpkin explained that consumers will participate in the kind of exchange that they are discussing through a personal health record (PHR.) He does not envision individual consumers being entities in this exchange.

- With regard to exchange within the borders of a single state, John Lumpkin explained that if there is a state HIE, then that is how exchange will occur. If the exchange crosses state lines, then the environment that is created with the standards the Workgroup is discussing will ensure that this exchange is trustworthy.

- The distinction was made between certification and accreditation. John Lumpkin explained that a tool is certified; an entity is accredited. When trying to describe an individual using a certified health record to exchange information in a way that is consistent with the constructs of privacy and security (which may be an accreditation), then the entire process could be encompassed in the single term of validation.

- David Blumenthal explained that if the ONC were going to recognize validating groups, it would do so on a competitive basis. Certifying bodies could also compete to be validators.

- Paul Egerman asked if the Workgroup had considered a process by which validation is limited to a simple set of technical interoperability and security provisions. John Lumpkin explained that this industry is different than others in that people in this country are very concerned about the security of their health information. For example, people will forego care, they will not get their medications, etc. because they are concerned about their privacy. So this Workgroup, and the HITPC overall must always work with the awareness that this system of HIE can only exist if there is confidence in it on the part of the public and providers.

- Neil Calman commented that the real risks take place at the provider level. He does not know of a mechanism, beyond what is already in place, to ensure that when the information gets into the hands of someone else, it will be used appropriately.

- David Lansky cautioned against handing off some of the difficult governance problems to a non-government organization.

- David Blumenthal suggested that the Workgroup set up their recommendations more clearly as directional, and bring them back to the Committee for further discussion at its next

meeting. He suggested breaking the work into chunks and bringing the Workgroup back to the HITPC with priority assigned to issues that are broadly directional and those that are time sensitive. Deven McGraw asked that the Workgroup also present more detail about what this private entity would look like.

5. Information Exchange Workgroup Recommendations

Information Exchange Workgroup Chair Micky Tripathi presented the latest set of recommendations concerning provider directories, reporting on the most recent deliberations related to one set of provider directories, and introducing what will be happening with another set of directories in the next month.

The Workgroup is discussing two directories—entity-level provider directories, and individual-level provider directories. The distinguishing characteristic is how much detail is contained. The-entity level directory contains information about organizations, but not necessarily about the individuals who make up organizations or entities. The individual-level directory provides information at the level of individual providers. At the next HITPC meeting, the Information Exchange Workgroup will present recommendations on policy with regard to the creation of entity-level directories, and then it will offer recommendations on individual-level provider directories. At this meeting, Micky Tripathi presented the recommended characteristics of provider directories.

The Workgroup broke down the subject into two broad areas of activity, requirements and options of provider directories. Taken together, they define the characteristics of entity-level directories. Micky Tripathi presented a set of recommendations outlining the categories of that framework, including:

- Users: The following entities should be listed in the entity-level provider directories: (1) health care provider organizations (e.g., hospitals, clinics, nursing homes, pharmacies, labs, etc.); (2) other health care organizations (e.g., health plans, public health agencies); (3) health information organizations (e.g., regional HIE operators, health information service providers); and (4) other organizations involved in the exchange of health information (e.g., business associates, clearinghouses).

- Uses and Functionality: Entity-level provider directories should support the following functionalities: (1) support directed exchanges (send/receive as well as query/retrieve); (2) provide basic "discoverability" of entity; (3) provide basic "discoverability" information exchange capabilities (e.g., CCD, HL7 2.XX); and (4) provide basic "discoverability" of entity's security credentials.

- Content: Entity-level provider directory content should be limited to the following categories of information: (1) entity "demographics" and identification information, (2) information exchange services, and (3) security.

- Business Models: The business model and operating approach should be an Internet-like model (i.e., a nationally coordinated, federated approach). This has the benefits of national

scalability, interoperability across regions/HIEs, and is relatively simpler to implement. Issues to be mindful of include data management and conformance across industry.

Micky Tripathi then presented a set of policy questions that the workgroup will be discussing and bringing back to next month's HITPC meeting. These include: which business models should the government promote? What are the potential government roles and levers? What is the appropriate level of depth in policy recommendations? What is critical and necessary to meet our goals?

In discussion, the following points were made:

- In reply to a question about addressing e-mail correspondence, Micky Tripathi explained that it would be up to the entity to make sure that the correspondence gets from its front door to its intended recipient. Somewhere in the header or in the message, there would need to be the key to allow onward routing, but that is not information that would be needed in the entity-level provider directory.

- Paul Egerman noted that the entity-level provider directory could be a directory of all participants in NHIN, perhaps with a superset that is larger than that. This could then tie into the governance issue.

- Art Davidson raised the issue of role-based messages, in which the sender does not know the person who should receive it, but rather their role. Also, he asked whether there are directory models that exist in other industries, such as banking or telecommunications. Micky Tripathi indicated that he does not know enough about other industries to speak to whether they have directory models to offer, but he did comment that health care is one of the most fragmented industries in the U.S. economy.

> **Action Item #2:** The Committee accepted the recommendations of the Information Exchange Workgroup by consensus.

6. Privacy and Security Tiger Team Recommendations

Privacy and Security Tiger Team Chair Deven McGraw presented the objective and scope of the Team's discussion:

- Stage 1 of meaningful use includes some requirements to exchange identifiable clinical information among providers for treatment purposes—the Tiger Team expects that the exchange requirements will increase in Stages 2 and 3.

- The Team focused on a trust framework for information exchange between EHR systems.

- There is a need to validate that the organization is who it says it is (digital credentials). For example, does the organization really exist, and how can one gain assurance that someone else is not spoofing or assuming the organization's identity?

- The Team is evaluating these trust rules at the organizational or entity level, and as such, the scope of this recommendation does not include authentication of individual users of EHR systems.

- With respect to individual users, provider entities and organizations must develop and implement policies to identity proof and authenticate their individual users (this is already required under the Health Insurance Portability and Accountability Act [HIPAA] Security Rule).

Privacy and Security Tiger Team Co-Chair Paul Egerman explained that on the Internet, the identity of an entity is authenticated using a digital certificate, which contains information about the entity and a public encryption key that, when used in combination with its paired private key (retained by the entity), can be used to authenticate the identity of the certificate holder. The process of assigning a digital certificate to an entity is called credentialing. This digital certificate is necessary, but it is not sufficient as the only measure of security.

Paul Egerman offered the Tiger Team's recommendations in six areas: (1) which provider entities should be issued digital certificates, (2) requirements to be issued digital certificates, (3) the process for issuing digital certificates and the process for re-evaluation, (4) characteristics of who can credential/issue digital certificates, (5) EHR certification and standardization of digital certificates, and (6)types of transactions requiring certificates. He explained that the aim is to create a process around digital certificates, to create standards and criteria, and make it required as part of the certification process. This is not just about the certification of systems, but it touches on governance. The Tiger Team acknowledges that multiple credentialing organizations are needed, but the governing agency has to be in control.

The discussion that followed included the following highlights:

- Adam Clarke asked whether validation of a user's identity is going to be required as things progress through Stages 2 and 3 of meaningful use and patients are interacting with systems. Paul Egerman noted that in its first recommendation, the Tiger Team included a group called PHR providers. The basic concept is still at an entity level: an organization is providing PHR systems to patients, and if a patient wants their information sent electronically, this is how they can be assured that the transaction is going to the correct place. However, this does not address whether the patient is who he says he is. It does not address identification all the way to the individual level; the Tiger Team will be addressing that issue separately.

- Deven McGraw explained that the Tiger Team wants to be sure that there is an accountable process where health care credentialing is concerned (e.g., ensuring that the business in question is a valid business, and that it deals with health care). The Team is not trying to limit this only to meaningful users. Wherever this health information goes, the sender must know who the receiving party is, but the process is not necessarily limited to meaningful use.

- Larry Wolf pointed out that there are other ways to secure communications between entities. Existing exchanges have already implemented some kind of security, given that they are operating under HIPAA requirements. He wondered whether scoping would help to

distinguish between existing point-to-point communications that health care providers have already set up, and moving into the much more populated world of many-to-many in health care communication. Paul Egerman likened this to creating standards for lab test results. It is beneficial to have those standards, but it is not necessary to change what is already set up. This should be done in such a way that organizations do not change what they already have. Deven McGraw added that these recommendations are being created for people who do not already have something set up.

- It was noted that auditability will be addressed in detail, but those issues are not discussed in these recommendations. Audit issues should be handled as part of the transparency recommendations.

- The Committee agreed that the term "meaningful use" should be changed to "electronic health care transactions" in the Tiger Team's recommendations.

> **Action Item #3:** The Committee approved the tiger team's recommendations by consensus, with the term "meaningful use" being changed to "electronic health care transactions."

7. Public Comment

- Carol Bickford of the American Nursing Association asked that the Committee include other clinicians in their discussions. She reminded Committee members that there are approximately 3.1 million registered nurses, along with other colleagues who are not physicians.

- Samantha Birch from the Federation of American Hospitals commented on the Privacy and Security Tiger Team's work. She commented that some of their recommendations may be outside of the scope of authority given to the Department of Health and Human Services. One example is the discussion around informed consent, and other exchanges outside of HIPAA. Consent is not required under Health Information Technology for Economic and Clinical Health Act, or under HIPAA. She suggested that the Privacy and Security Tiger Team could benefit from greater input from the hospital, clinic, and academic communities.

SUMMARY OF ACTION ITEMS:

Action Item #1: Minutes from the October 20, 2010, HITPC meeting were approved by consensus.

Action Item #2: The Committee accepted the recommendations of the Information Exchange Workgroup by consensus.

Action Item #3: The Committee approved the tiger team's recommendations by consensus, with the term "meaningful use" being changed to "electronic health care transactions."